

Serial No. 08/444,790
Filed: May 19, 1995

New claims 62-77 have been added. Accordingly, claims 62-77 are pending in the subject application.

Before addressing the merits of the Office Action, applicants wish to thank Examiners Murphy and Mertz for extending applicants' attorneys the courtesy of an interview on May 4, 2000. At the interview, the Examiners and applicants' attorneys discussed the Office Action, the documents cited therein, and the relevance of the cited documents to the claimed invention. As noted in the interview summary, the above amendments, which incorporate sequence data, should obviate all rejections based on 35 U.S.C. §112. Olsson et al. [*Eur. J. Haematol.*, 42: 270-275 (1989)] was acknowledged at the interview not to teach or suggest applicants' invention because it discloses a different amino acid sequence and molecular weight. Accordingly, all rejections under 35 U.S.C. §§102 and 103 should be obviated. To assist the Examiner in completing a thorough search, applicants enclose a courtesy disk containing the sequence listing in Figure 1, a paper version of the sequence listing, and a declaration that the disk and the paper version are the same and represent the sequence in Figure 1.

In the Office Action, the Patent Office rejected claims 44, 46, 57-58, and 60 under 35 U.S.C. §112, first paragraph. The rejections were based on alleged non-enablement of tumor necrosis factor ("TNF") receptor polypeptides other than those exemplified in the specification, in particular protein fragments, alleged failure to reasonably convey that the inventors had possession of the claimed invention, and alleged definition of the claimed protein by function alone. While the Patent Office acknowledged that the specification is "enabling for homogeneous protein comprising an amino acid sequence set forth in Figure 1," it alleged that the specification does not "reasonably provide enablement for amino acid sequences that are fragments of said sequences."

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To expedite prosecution, applicants have incorporated, in whole or in part (the part being specifically defined), the amino acid sequence of Figure 1 in all newly presented claims. Thus, all claims explicitly recite the detailed composition of the proteins being claimed. With regard to fragments, applicants have restricted such fragments to comprise the first approximately 180 amino acids in Figure 1, and even more specifically, in dependent claims, to amino acids 1-180 and 1 to 182. Support for these claims can be found on page 35, lines 11-18 (describing the N-terminal domain as containing approximately 180 amino acids), Example 9 (describing the production of a DNA plasmid incorporating the cDNA coding for the extracellular part of the 55kD TNF-BP and its expression), and Figure 1 (showing amino acids 1-182 as the extracellular domain).

In view of the above, applicants request withdrawal of all rejections under 35 U.S.C. §112, first paragraph.

Claims 46, 58, and 60 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for reciting the term “fragment,” which was alleged to encompass potentially any portion of the polypeptide including a single amino acid.

Applicants’ claims no longer recite the term “fragment.” The only “fragments” now claimed are specific and incorporate the amino acid sequence of Figure 1 beginning at amino acid number 1 and ending approximately at amino acid number 180. Dependent claims specifically recite amino acid sequences that begin at amino acid number 1 and end at amino acid number 180 or begin at amino acid number 1 and end at amino acid number 182. All claimed proteins must bind human TNF.

In view of the above, applicants request withdrawal of all rejections under 35 U.S.C. §112, second paragraph.

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Claims 44-45 and 56 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Olsson et al. [*Eur. J. Haematol.*, 42: 270-275 (1989)] and under 35 U.S.C. §103 as allegedly obvious over Olsson et al. in view of Miles et al. [*B. Med. J.*, 299: 1019-1022 (1989)]. Olsson et al. was alleged to disclose the purification to homogeneity of a soluble TNF binding protein that comprises the amino sequence set forth in applicants' Figure 1; Miles et al. was alleged to teach the use of recombinant DNA technology to express cloned cells; and the combination of Olsson et al. and Miles et al. was alleged to make obvious the recombinant manufacture of the TNF binding protein.

As explained at the interview, Olsson et al. does not disclose applicants' claimed proteins. In the absence of such disclosure, the disclosure of Miles et al. becomes irrelevant.

Olsson et al. discloses isolation of a tumor necrosis factor binding protein from urine. The aminoterminal amino acid sequence was identified as D-S-V-X-P-Q-G-K-Y-I-H-P-Q-V-N-S-I-X-K-T. These twenty amino acids are different from the aminoterminal amino acid sequence that is included in all of applicants' claimed proteins. (See amino acids 1-20 in applicants' Figure 1 for comparison.) Moreover, Olsson et al. discloses that their tumor necrosis factor binding protein has an apparent molecular weight of 30,000 on SDS-PAGE. In contrast, applicants describe a tumor necrosis factor binding protein that has an apparent molecular weight of 55,000. Therefore, Olsson et al. does not teach or suggest applicants' claimed proteins.

In view of the above, applicants request withdrawal of all rejections under 35 U.S.C. §§102 and 103.

In reviewing the prosecution, it has come to applicants' attention that the initialed FORMs PTO-1449 filed February 25, 1997 (listing documents A5, B13, and C23-26) and July 14, 1998

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(listing document A6) have not been returned to applicants. Copies of these forms are enclosed for your convenience. Consideration of all documents cited therein and return of the initialed FORMs PTO-1449 is solicited.

In summary, applicants request reconsideration, withdrawal of all rejections, and the issuance of a Notice of Allowance.

If a telephone conference would be of assistance in furthering prosecution of the subject application, applicants request that the undersigned attorney be contacted at the number below.

No fee is required in connection with the filing of this Amendment. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,



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